

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

10/05/2007

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NEW YORK STATE RESTAURANT
ASSOCIATION,

Plaintiff,

NOTICE OF APPEAL

07 CV.5710

- against -

NEW YORK CITY BOARD OF HEALTH, et al.,

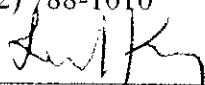
Defendants.
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PLEASE TAKE NOTICE that defendants hereby appeal to the United States Court of Appeals, Second Circuit from the opinion and order (one paper) of the Hon. Richard J. Holwell herein dated September 11, 2007. This appeal is taken from each and every part of said opinion and order (one paper) as well as from the whole thereof.

Dated: New York, New York
October 5, 2007

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CLERK
Southern District

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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NEW YORK STATE RESTAURANT
ASSOCIATION, :

Plaintiff, :

-against- :

NEW YORK CITY BOARD OF HEALTH, et al., :

Defendants. :
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07 Civ. 5710 (RJH)

MEMORANDUM OPINION
AND ORDER

In this action, the New York State Restaurant Association ("NYSRA"), a not-for-profit business association of over 7,000 restaurants, challenges a regulation recently enacted by the City of New York. New York City Health Code § 81.50 ("Regulation 81.50") would require New York City restaurants who already make the calorie content information of their menu items publicly available to post such information on their menu boards and menus. This regulation would affect roughly ten percent of restaurants in New York City, including so-called chain restaurants such as McDonald's.

NYSRA argues that this regulation is invalid because it is expressly preempted by the Nutrition Labeling and Education Act of 1990 ("NLEA"), 21 U.S.C. §§ 301, 343, 343-1 (2006). NYSRA also contends that Regulation 81.50 is unconstitutional because the regulation violates its members' First Amendment rights. It has moved for partial summary judgment and declaratory relief on its preemption claim and seeks a preliminary injunction on its First Amendment claim. New York City ("the City"), in turn, seeks summary judgment in its favor on the preemption claim. Appearing as amici curiae are

public officials, citizen advocacy groups, non-profit medical associations, law and health professors, cities, counties, and municipal associations, all supporting the regulation.¹

For the reasons that follow, the Court concludes that the City has the power to mandate nutritional labeling by restaurants, but that it has done so in a manner that offends the federal statutory scheme for voluntary nutritional claims. Therefore, the City's regulation, as enacted, is preempted by federal law. The Court does not reach the plaintiff's First Amendment claims.

BACKGROUND

On December 5, 2006, the Department of Health and Mental Hygiene ("the Department") adopted Regulation 81.50. Initially to take effect on July 1, 2007, it applies to standardized menu items "for which caloric content information is made publicly available on or after March 1, 2007." Because its application is limited to restaurants that make public the caloric value of their food, the Regulation only affects an estimated 2,375 food service establishments of more than 23,000 permitted establishments in New York City. (Decl. of Thomas R. Frieden ("Frieden Decl.") ¶ 49.) The regulation requires such restaurants to "post on menu boards and menus the caloric content values . . . for each menu item next to the listing of each menu item . . . in a size and typeface at

¹ Specifically, three amici briefs were filed. The first was submitted on behalf of the Jennifer L. Pomeranz and Kelly D. Brownell of the Rudd Center for Food Policy and Obesity at Yale University and Robert Post, Constitutional Law professor at Yale Law School. The second was submitted by U.S. Representative Henry Waxman, former FDA Commissioner David Kessler, Public Citizen, Center for Science in the Public Interest, American College of Preventive Medicine, American Diabetes Association, American Medical Association, American Public Health Association, California Center for Public Health Advocacy, The Medical Society of the State of New York, Trust For America's Health, and professors of medicine, nutrition and public health. ("Waxman Amici.") The third was submitted on behalf of the City and County of San Francisco; the cities of Philadelphia, Pennsylvania, Baldwin Park, California, Palo Alto, California, and West Hollywood, California; the County of Los Angeles, California, King County, Washington, and Montgomery County, Maryland; National League of Cities, National Association of County & City Health Officials, International Municipal Lawyers Association, and League Of California Cities; California State Senators Alex Padilla and Carole Migden, New York State Assemblyman Felix Ortiz, Chicago Alderman Edward M. Burke, and Washington D.C. Councilmember Phil Mendelson. ("San Francisco Amici.")

least as large as the name of the menu item or price, whichever is larger.” Where menu items have varying calorie counts depending on flavor and variety, but are listed as a single menu item, the range of values may be listed. Finally, subject to approval by the Department, restaurants may use alternate means of communicating this information to customers provided the display is “at least as prominent.” The Department was to begin performing inspections and issuing violations on July 1, 2007, although the City provided a three-month grace period before fines were levied. (Frieden Decl., Ex. 12.) However, in order to allow the issues discussed herein to be more fully briefed, the City agreed to stay the enforcement of Regulation 81.50 until October 1, 2007, including issuing warning letters, notices of violations, and violations. (See June 27, 2007 Stipulation and Order.)

In explaining its policy reasons for issuing Regulation 81.50, the City describes an “obesity epidemic” in America generally, and New York specifically. (Frieden Decl. ¶ 3 (proportion of obese Americans rose from 14.5% in 1971–1974 to 32.2% in 2003–2004).) In New York City, more than half of adults are overweight (34.4%) or obese (21.7%). (*Id.*) People who are overweight or obese are at increased risk of a wide range of serious health problems, including diabetes, heart disease, stroke, and cancer. (Frieden Decl. ¶¶ 9–12.) In addition to human costs, these health problems generate enormous financial costs to society. (Frieden Decl. ¶ 13.) The City contends that calories are the single most important piece of nutritional information related to weight gain, as it results from an imbalance between calories consumed (nutrition) and energy expended (physical activity). (Frieden Decl. ¶ 14, 19–20.) Furthermore, Americans receive an estimated one-third of their caloric intake away from home. (Frieden Decl. ¶¶ 4, 16.) At present,

there are no nutrition labeling requirements for restaurants and what nutrition information is voluntarily provided is only seen by a small fraction of restaurant patrons, leading consumers to underestimate the caloric content of their away-from-home meals. (Frieden Decl. ¶¶ 29, 32.) Based on these facts, the City argues that Regulation 81.50 has “substantial potential for public health impact,” as consumers are likely to decrease caloric intake and restaurants are encouraged to offer less caloric food options. (Frieden Decl. ¶¶ 49, 50.)

New York City is not alone in this belief. Accompanying an amici brief submitted to the Court were seventeen pieces of legislation passed or being considered by states, counties, and cities that require restaurants to disclose nutrition information. (San Francisco Amici, Exs. A–S.) While some of these bills make the disclosures contingent on the restaurant having already provided voluntary nutrition information, as is the case here, most simply mandate chain restaurants (variously defined) to post nutrition information on their menu boards. As discussed below, this distinction is critical to an analysis of whether such state and local regulations are preempted by existing federal law.

NYSRA, not surprisingly, voices objections to the City’s choice of methods for combating obesity, although not the goal itself. First, NYSRA argues that caloric intake is just one component of a healthy lifestyle, and its reduction is not a “magic bullet” to combat obesity. (Pl.’s Mem. of L. in Support (“Mem. of L.”) 3.) By posting only caloric content for menu items, the NYSRA suggests that restaurants will be forced to communicate a message with which they disagree, that calories are the only important piece of nutrition information. (*Id.* at 5, 7.) Second, the NYSRA contends that it is far

from clear that consumers will be able to effectively utilize caloric information, or that the method chosen, posting caloric content on menu boards, is a superior means of communicating with patrons. (Mem. of L. 7, 27; Decl. of David B. Allison 24.) The restaurants subject to Regulation 81.50 are already providing comprehensive nutrition information through a variety of methods, including websites, posters, on-package labeling, and tray liners, that the NYSRA suggests are effective. (Mem. of L. 5.) Third, Regulation 81.50 requires restaurants to post caloric content on menu boards, the “most valued space in the restaurant.” (*Id.* at 7.) The NYSRA asserts that by specifying the location and size for such information, the regulation will make menu boards confusing and are likely to adversely impact restaurants to which the regulation applies.

Both parties and amici argue about, and attach voluminous affidavits, declarations, and exhibits devoted to, the wisdom of Regulation 81.50 as an effective means of reducing obesity and improving public health. The initial issue before the Court is not whether this is so, but whether the labeling regulations adopted here are properly within the City’s province or exclusively a matter for federal regulation.² Because the City has chosen a regulatory approach that imposes different obligations than federal regulation of voluntary nutritional claims made by restaurants, the Court is compelled to find that Regulation 81.50 as drafted is preempted by federal law.

DISCUSSION

Summary judgment is appropriate “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a

² Were the Court to reach the First Amendment question, it would then be appropriate to consider governmental objectives.

judgment as a matter of law.” Fed. R. Civ. P. 56(c). Both sides agree that there are no genuine issues as to any fact material to the question of preemption. In this instance, preemption is a legal question for the Court to decide. *See Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190, 201 (1983) (“The question of pre-emption is predominantly legal.”). Therefore, it is ripe for summary judgment.

Plaintiff contends that the NLEA preempts Regulation 81.50. Under the Supremacy Clause, state law³ that conflicts with federal law⁴ is without effect. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). However, “because the States are independent sovereigns in our federal system, [courts] have long presumed that Congress does not cavalierly pre-empt state-law causes of action.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). Particularly “[i]n areas of traditional state regulation, [courts] assume that a federal statute has not supplanted state law unless Congress has made such an intention ‘clear and manifest.’” *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005) (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)); *see also Medtronic, Inc.*, 518 U.S. at 485 (where “Congress has legislated . . . in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” (citations and internal quotations marks omitted)).

³ “[F]or the purposes of the Supremacy Clause, the constitutionality of local ordinances is analyzed in the same way as that of statewide laws.” *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985).

⁴ “Federal regulations have no less pre-emptive effect than federal statutes” provided the administrator neither “exceeded his statutory authority [n]or acted arbitrarily.” *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153-154 (1982).

This presumption is clearly applicable to the present case, where the City regulation addresses concerns about the health of its citizens. The regulation of “matters of health and safety . . . is a sphere in which the presumption against preemption applies, indeed, stands at its strongest.” *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94 (2d Cir. 2007); *see also Med. Soc’y of the State of N.Y. v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992) (“The regulation of public health and the cost of medical care are virtual paradigms of matters traditionally within the police powers of the state.”).

“Identifying congressional purpose is the ‘ultimate touchstone’ of a preemption inquiry.” *N.Y. State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115, 119 (2d Cir. 1989) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)). Intent to preempt may be express or implied. The NLEA explicitly forecloses the possibility that state law would be impliedly preempted. *See* Pub. L. No. 101-535, § 6(c), 104 Stat. 2535, 2364 (“The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [§ 343-1] of the Federal Food, Drug, and Cosmetic Act.”). Therefore, preemption is limited to the express preemption provisions found in 21 U.S.C. § 343-1(a).

To determine the scope of an express preemption provision, courts look to “the language of the pre-emption statute and the statutory framework surrounding it.” *Medtronic, Inc.*, 518 U.S. at 486 (citations omitted). The Court must “identify the domain expressly pre-empted” by the preemption provision and determine whether it encompasses the state law at issue. *Cippoline*, 505 U.S. at 517. To the extent there is any ambiguity in the preemption provision, the presumption against preemption in a field of regulation that states have traditionally occupied requires a narrow interpretation of the

express provision. *See Medtronic, Inc.*, 518 U.S. at 485; *see also Bates*, 544 U.S. at 449 (Court has “duty to accept the reading [of the express preemption provision] that disfavors preemption,” even where the party seeking preemption advances a “just as plausible” reading of the text). Before discussing the express preemption provisions of the NLEA, it is useful to consider the structure of the NLEA as a whole. *See Medtronic, Inc.*, 518 U.S. at 486 (relevant to “any understanding of the scope of a pre-emption statute . . . is the structure and purpose of the statute as a whole.” (internal quotation marks and citations omitted)).

A. Nutrition Labeling and Education Act of 1990

In 1990, Congress passed the NLEA, Pub. L. No. 101-535, 104 Stat. 2535 (1990), requiring labeling on all packaged foods and regulating the making of claims concerning food. *See* 21 U.S.C. §§ 343(q), (r). The House Report accompanying the bill described the dual purposes as follows: “to clarify and to strengthen the Food and Drug Administration’s legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods.” H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337. The NLEA added two new subsections (§§ 343(q) and (r)) to the Federal Food, Drug, and Cosmetic Act, which was originally enacted in 1938, and which generally prohibits the misbranding of food.

1. Mandatory Nutritional Labeling

The first subsection of the NLEA, 21 U.S.C. § 343(q), designates a “food intended for human consumption and [] offered for sale” as misbranded if its label fails to bear certain required “nutrition information.” 21 U.S.C. § 343(q)(1). The familiar “Nutrition Facts” panels on the back of packaged foods are mandated by this subsection.

Pursuant to § 343(q) and Pub. L. No. 101-535, § 2(b)(1), the FDA enacted regulations establishing guidelines for the nutrition labeling of food. *See* 21 C.F.R. §§ 101.1- 9 (2007). Because Congress found that full nutritional labeling of restaurant food would be “impractical,”⁵ H.R. Rep. No. 101-538, at 7, the NLEA expressly exempted food served in restaurants from mandatory nutrition labeling. *See* 21 U.S.C. § 343(q)(5)(A)(i).⁶

2. Voluntary Nutrient Content Claims

The second subsection of the NLEA, 21 U.S.C. § 343(r), designates a food as misbranded if “a claim is made in the label or labeling of the food which expressly or by implication . . . characterizes the level of any nutrient” unless “the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary.” 21 U.S.C. §§ 343(r)(1)(A), (2)(A)(i). Examples of such claims include “low sodium,” “lite,” or “high in oat bran.” H.R. Rep. 101-538, at 19. Unlike § 343(q), this subsection and its requirements only apply where a purveyor voluntarily chooses to make a covered claim. Subsection (r) expressly exempts “statement[s] of the type required by paragraph (q) that appear[] as part of the nutrition information required or permitted by” that subsection. 21 U.S.C. § 343(r)(1). Pursuant to § 343(r) and Pub. L. No. 101-535, § 3(b)(1), the FDA enacted regulations governing nutrient content claims, including uniform definitions of descriptors (e.g. lite, good source, or contains) and claims describing particular nutrients (e.g. calorie free or reduced sodium). *See* 21 C.F.R. §§ 101.10, 101.13, 101.54- 65 (2007).

⁵ According to amici, Congress made this determination after mandatory nutrition labeling for restaurants was “vociferously opposed” by the National Restaurant Association. (Waxman Amici 8.)

⁶ If a restaurant chooses to make nutrition information available, it can either comply with the nutrition labeling requirements of 21 C.F.R. § 101.9 or the far more flexible requirements of 21 C.F.R. § 101.10 governing restaurants. *See* FDA, Food Labeling: Questions and Answers, Volume II, “A Guide for Restaurants and Other Retail Establishments” (Aug. 1995), at R76.

In contrast to subsection (q), restaurants are not exempt from subsection (r). *See* 21 U.S.C. § 343(r)(5)(B). Thus, if a restaurant voluntarily chooses to make a nutrient content claim in the label or labeling of its food, including on menus, such a claim must be in compliance with FDA regulations. *See* 21 C.F.R. § 101.13(q)(5) (“A nutrient content claim used on food that is served in restaurants . . . shall comply with the requirements of this section.”); *Reyes v. McDonald’s Corp.*, No. 06 C 1604, 2006 U.S. Dist. LEXIS 81684, at *14 (N.D. Ill. Nov. 8, 2006) (where defendant restaurant posted nutritional charts on website, it subjected itself to the provisions of the NLEA labeling requirements); *see also Public Citizen v. Shalala*, 932 F. Supp. 13, 18 (D.D.C. 1996) (ordering FDA to regulate claims made in restaurant menus under § 343(r)). In addition to complying with the general regulations governing claims, a restaurant making a claim that characterizes the level of any nutrient must provide upon request “the nutrient amounts” of that particular food or meal “that are the basis for the claim.”⁷ 21 C.F.R. § 101.10. This regulation gives restaurants flexibility in the manner and location in which they present such information and the methodology in which those nutrient levels are determined. *Id.* Thus, there is no requirement under the federal regulations that the nutrient amounts be displayed in the manner required by Regulation 81.50.

3. Preemption Provisions

The NLEA also added two express preemption provisions to 21 U.S.C. § 343-1(a) applicable to the newly added subsections. Section 343-1(a)(4) provides that “no State or political subdivision of a State may directly or indirectly establish under any authority . . .

⁷ For example, if a restaurant declares an item to be “low fat,” it must provide its fat content, or the approximate fat content if the exact amount of fat is unknown. Such information is considered the “functional equivalent of complete nutrition information as described in 21 C.F.R. § 101.9.” 21 C.F.R. § 101.10.

any requirement for nutrition labeling of food that is not identical to the requirement of [§ 343(q)], except a requirement for nutrition labeling of food which is exempt under” § 343(q)(5)(A). Subsection (q)(5)(A) exempts “food . . . which is served in restaurants” from mandatory nutritional labeling. 21 U.S.C. § 343(q)(5)(A). Thus, states are not precluded under § 343-1(a)(4) from establishing requirements for the mandatory nutrition labeling of restaurant food. *See Pelman v. McDonald’s Corp.*, 237 F. Supp. 2d 512, 526 (S.D.N.Y. 2003) (“§ 343-1(a)(4) does not expressly bar [state-mandated] nutrition labeling on restaurant foods either directly or . . . indirectly.”); *see also* 136 Cong. Rec. S16607 (Oct. 24, 1990) (Sen. Metzenbaum) (“Because food sold in restaurants is exempt from the nutrition labeling requirements of [§ 343(q)], the bill does not preempt any State nutrition labeling requirements for restaurants.”); FDA, Food Labeling: Questions and Answers, Volume II, “A Guide for Restaurants and Other Retail Establishments” (Aug. 1995), at ¶ R31 (“[B]ecause the act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted.”).

By contrast, states are broadly preempted from regulating voluntary claims that characterize the level of any nutrient, including, as noted, those made by restaurants. Thus, section 343-1(a)(5) provides that “no State or political subdivision of a State may directly or indirectly establish under any authority . . . any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r),” except in circumstances not applicable here. Therefore, states are precluded under § 343-1(a)(5) from establishing

requirements for “claims,” including those made by restaurants, unless the requirements are identical to federal requirements.⁸

The issue for resolution, then, is whether Regulation 81.50 is a permitted state regulation under section 343-1(a)(4) or a prohibited state regulation under section 343-1(a)(5). The City contends that it is imposing a requirement for nutrition labeling of restaurant food, which is expressly exempted from preemption under §343-1(a)(4). NYSRA argues that the disclosure of calorie content information that triggers Regulation 81.50 is a “claim,” subjecting the disclosure to regulation under § 343(r) and thus to preemption under § 343-1(a)(5). If the disclosure does not constitute a “claim” within the scope of § 343(r), then NYSRA’s argument fails as the preemption provision in § 343-1(a)(5) is inapplicable on its face. Thus, the first question the Court must answer is whether calorie content information can be a “claim” within the scope of § 343(r).

B. Can a Factual Statement of Calories Be a “Claim” under § 343(r)?

This inquiry must begin with the text of the statute. Section 343(r) applies to “a claim [] made in the label or labeling of [] food” that “expressly or by implication characterizes the level of any nutrient.” 21 U.S.C. § 343(r). Both the noun “claim” and the verb “characterize” suggest a statement (subject to justification) of the character or quality of the modified object, in this case the level of any nutrient (e.g. “low calorie” or “high fiber”), as opposed to a simple (uncontestable) factual disclosure (e.g. “100 calories” or “2 grams fat”). See Webster’s Third International Dictionary 414 (2002) (defining “claim” as “an assertion, statement, or implication (as of value, effectiveness, qualification, eligibility) often made or likely to be suspected of being made without

⁸ 21 U.S.C. § 343-1 also provides that “a State or political subdivision of a State” may petition the FDA for an exemption from these preemption provisions if it would not, *inter alia*, “unduly burden interstate commerce.” 21 U.S.C. § 343-1(b). No petition was made in this case.

adequate justification”); *id.* at 376 (defining ‘characterize’ as “to describe the essential character or quality of,” as in characterize “a friend in a few words”). The examples given in the legislative history are consistent with the plain language of the statute and indicate the heartland of claims covered by § 343(r): “lite,” “high fiber,” “low cholesterol,” and “less than 1% fat.” 136 Cong. Rec. H5836 (July 30, 1990). These common sense examples also appear consistent with the dual statutory structure of the NLEA whereby factual statements of nutrient amounts are mandated in § 343(q), while claims that characterize the level of any nutrient are regulated by § 343(r).

Considering unadorned, factual statements of nutrient amount to fall outside the scope of § 343(r) finds some support in statements by the FDA. In the preamble to the regulations implementing § 343(r), the FDA observed that “there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food,” and provides as examples “100 calories” and “5 grams of fat.” 58 Fed. Reg. 2302, 2310 (Jan. 6, 1993). Similarly, the FDA has stated that a food purveyor may make an “accurate quantitative statement (e.g., 200 mg of sodium) that does not ‘characterize’ the nutrient level.” FDA, Ctr. For Food Safety and Applied Nutrition, *Claims That Can Be Made for Conventional Foods and Dietary Supplements* (Sept. 2003). If, as the FDA appears to recognize, such statements do not “characterize” a nutrient level, then under the clear text of § 343(r), the FDA would not have authority to regulate them.

However, the FDA regulations take a considerably broader view of the scope of the agency’s authority under § 343(r). 21 C.F.R. § 101.13 implements § 343(r) by prohibiting any “claim that expressly or implicitly characterizes the level of a nutrient”

unless made in accordance with FDA regulations governing such claims. 21 C.F.R. § 101.13(b). This is consistent with the language of § 343(r). However, the regulation continues, “[a]n expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘contains 100 calories.’” 21 C.F.R. § 101.13(b)(1). This definition appears to cover both an obvious characterization (“low sodium”) as well as a simple statement about the amount of a nutrient in a food (“contains 100 calories”).⁹

Furthermore, “statement[s] about the amount or percentage of a nutrient” are specifically regulated by 21 C.F.R. § 101.13(i).¹⁰ *See also* Pub. L. No. 101-535, § 3(b)(1)(A)(iv) (directing the FDA to “permit statements describing the amount and percentage of nutrients in food.”). This paragraph permits a “statement [that does] not in any way implicitly characterize the level of the nutrient in the food and [is] not false or misleading in any respect.” 21 C.F.R. § 101.13(i)(3). While a simple numerical statement may not *implicitly* characterize a nutrient amount, the FDA takes the position that it does *expressly* characterize the level of the nutrient. *See* FDA, Food Labeling: Questions and Answers, Volume II, “A Guide for Restaurants and Other Retail Establishments” (Aug. 1995), at ¶ R94 (“[I]n a statement that includes a quantitative declaration, e.g., ‘contains 2 grams of fiber,’ the amount of fiber in the food is

⁹ Amici argue that the word “contains” is a nutrient content claim in the foregoing example, and without it, “100 calories” would not be a claim. The FDA has explained that “contains” can either be a nutrient content claim or a “simple verb” depending on how it is used. FDA, Food Labeling: Questions and Answers, Volume II, “A Guide for Restaurants and Other Retail Establishments” (Aug. 1995), at ¶ R94. In the phrase “contains fiber,” “contains” is a nutrient content claim meaning “good source” of fiber. *See* 21 C.F.R. § 101.54(c) (defining “contains”). In the phrase “contains 2 grams of fiber,” in contrast, “contains” is a “simple verb” and the FDA considers the quantitative declaration “2 grams” to be a nutrient content claim whether or not the word “contains” is employed. FDA, Food Labeling, at ¶ R94.

¹⁰ Under this paragraph, the FDA permits claims such as “less than 3 g of fat per serving” when the nutrient amount is consistent with a definition for a claim provided by FDA regulations, 21 C.F.R. § 101.13(i)(1), and claims such as “less than 20 g of fat per serving, not a low fat food,” when it is not, 21 C.F.R. § 101.13(i)(2).

characterized by the quantitative declaration, “2 grams.” (emphasis added)). Thus, the FDA regulations treat a simple factual statement as to nutrient amount as within the scope of § 343(r) and subject to (although expressly permitted by) FDA regulations.¹¹

This understanding of the regulations is further confirmed in the preamble of the regulations concerning the scope of § 343(r). Therein, the FDA addressed a comment seeking to exclude from the scope of regulations issued pursuant to § 343(r) “simple factual information about the nutrient content of a food.” 58 Fed. Reg. 2302, 2303–04 (Jan. 6, 1993). Answering the question now before the Court, the FDA concluded “that section [§ 343(r)] of the act and therefore these final regulations apply to statements of the amount of a nutrient in food [e.g. “5 grams fat”] as well as to statements of the level of a nutrient in food [e.g. “low fat”].” *Id.*

For all the foregoing reasons, the Court finds that under the FDA regulations, statements as to nutrient amount, including calorie content, *may* be a “claim” subject to the requirements of § 343(r) and its implementing regulations.^{12 13} A statement as to

¹¹ Moreover, 21 C.F.R. § 101.13(c) provides that “[i]f such information [as is required or permitted by § 343(q)] is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.” 21 C.F.R. § 101.13(c). While there is some ambiguity as to whether this information needs to be on the same label as a nutrition panel, or merely anywhere but a nutrition panel, this paragraph clearly envisions that a simple factual statement as to a nutrient amount can be a claim within the scope of § 343(r).

¹² Where there is an “express delegation of authority to the agency to elucidate a specific provision of the statute by regulation,” the “ensuing regulation is binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute.” *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (quoting *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843–44 (1984)). The court is not empowered to substitute its judgment for that of the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Under this standard, the Court finds the regulation to be binding. Factual statements as to nutrient amounts fall at the very periphery of claims regulated by § 343(r) and the FDA has chosen to include them.

¹³ The City also argues that the disclosure of calorie content information that triggers Regulation 81.50 is not covered by § 343(r) because it is not made “in the label or labeling of food.” (Def.’s Opp’n 11–12.) The Court finds this to be an overly narrow reading of labeling. “Labeling” is defined to include written, printed, or graphic material “upon any article or any of its containers or wrappers” or “accompanying such article.” 21 U.S.C. § 321(m). The Supreme Court has construed the term “accompanying such article” to include any item that “supplements or explains [the article]. No physical attachment one to the other is necessary.” *Kordel v. United States*, 335 U.S. 345, 350 (1948). Under this broad interpretation, menu,

nutrient amount is not a claim, however, when such a statement appears in the nutrient panel required by § 343(q). *See* 21 U.S.C. § 343(r)(1) (“A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph.”); 21 C.F.R. § 101.13(c) (“Information that is required or permitted by § 101.9 or § 101.36, as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section.”). Thus, it is clear that under the federal statutory scheme, the mandatory statement of nutrient amount in the familiar Nutrition Facts panel is not a “claim,” while an identical statement voluntarily made elsewhere on a food product label is a “claim” subject to § 343(r), the attendant FDA regulations, and, significantly, the broader preemption provision found in § 343-1(a)(5).¹⁴ Having established that the voluntary disclosure of calorie content information by restaurants that, as noted above, triggers Regulation 81.50 may be a “claim” under § 343(r), the Court must now consider whether Regulation 81.50 is thereby subject to the concomitant preemption provision found in § 343-1(a)(5).

C. Is Regulation 81.50 Preempted by § 343-1(a)(5)?

Although the Court’s analysis begins with the text of the preemption statute, the interpretation of that language does not occur in a “contextual vacuum.” *Medtronic, Inc.*, 518 U.S. at 485. As discussed earlier, the Court must keep in mind the presumption against preemption supporting a narrow interpretation of the preemption provision and

menu-boards, signs, placards, and posters would all be considered labeling of a food item. *See* 61 Fed. Reg. 40320, 40322 (Aug. 2, 1996) (menus are “labeling”); 58 Fed. Reg. 2302, 2388 (Jan. 6, 1993) (signs, placards, and posters are “labeling”). Therefore, the Court rejects the City’s argument against preemption on the ground that the claims were not made “in the label or labeling of food.”

¹⁴ That an identical statement may be both a claim and not a claim is not as inconsistent as may first appear. In the context of a voluntary statement made to its customers, the food purveyor is making an affirmative assertion as to the nutrient content of its product. In the context of a mandatory disclosure, the purveyor is making no claim at all; it is passively disclosing information as required by government regulations.

give effect to the structure and purpose of the statute as a whole. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (noting “fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme”).

The two preemption provisions accompanying § 343(q) and (r), § 343-1(a)(4) and (5) respectively, were passed in conjunction with one another. Section 343-1(a)(4) expressly carved out restaurants from the scope of NLEA’s preemption pertaining to required nutrition labeling. Both a sponsor of the Act and the agency responsible for adopting regulations enforcing the Act have recognized the authority of states to require restaurants to disclose nutritional content to its customers. *See* 136 Cong. Rec. S16607 (Oct. 24, 1990) (Sen. Metzenbaum)) (“Because food sold in restaurants is exempt from the nutrition labeling requirements of section 403(q)(1)–(4), the bill does not preempt any State nutrition labeling requirements for restaurants.”); FDA, Food Labeling: Questions and Answers, Volume II, “A Guide for Restaurants and Other Retail Establishments” (Aug. 1995), at ¶ R31 (“State requirements of the type required by [§ 343(q)] . . . would not be preempted for foods that are exempt from the Federal requirements. . . . [B]ecause the act exempts restaurant foods that do not bear a claim from mandatory nutrition labeling, State requirements for the nutrition labeling of such foods would not be preempted ”); *see also* 136 Cong. Rec. H5836 (July 30, 1990) (Rep. Waxman) (“[A]ny preemption provision must recognize the important contribution that the State can make in regulation, and it must leave a role for the states.”). New York City, then, would appear to be free to require restaurants to provide nutrition information.

Section 343-1(a)(5), on the other hand, preempts any state regulation of nutrient content claims, including claims made by restaurants, that “is not identical to the requirement[s] of section 403(r).” 21 U.S.C. § 343-1(a)(5).¹⁵ Under 21 C.F.R. § 101.10,¹⁶ a restaurant that makes a claim is allowed to publish the nutrient amount that is the basis for the claim “in various forms, including those provided in § 101.45 [shelf labels, signs, posters, brochures, notebooks, or leaflets] and other reasonable means.” Under Regulation 81.50, in contrast, a restaurant making calorie information available must post the amount of calories “on menu boards and menus.” Furthermore, under 21 C.F.R. § 101.10, a restaurant may determine the nutrient amount “by any reasonable bases” while under Regulation 81.50, the amount of calories must be “calculated in accordance with 21 C.F.R. § 101.9(c)(1)(i).” Thus, Regulation 81.50, as drafted, seems to impose “obligations . . . not imposed by or contained in” the federal regulation of nutrient content claims under § 343(r). 21 C.F.R. § 100.1(c).

As is now clear, there is tension between the exemption of state nutritional labeling requirements for restaurants from preemption under § 343-1(a)(4) and the broad

¹⁵ FDA regulations further define the phrase “not identical to” as follows:

“Not identical to” does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that (i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or (ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

21 C.F.R. § 100.1(c)(4).

¹⁶ The City argues that the FDA was without statutory authority to enact 21 C.F.R. § 101.10, and thus it is without preemptive effect. See *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 154 (1982). The Court finds that the FDA had authority to require restaurants to provide underlying nutrition information because it assists in compliance with the regulations. See 61 Fed. Reg. 40320, 40320–21 (Aug. 2, 1996) (“For compliance purposes, a restaurant is required to provide information on its reasonable basis for making a claim.”). Such authority then extends to specifying (or granting flexibility in) where such statements may be made, and how such information may be ascertained.

preemption of regulations respecting claims under § 343-1(a)(5). This tension is caused, in part, by the FDA's expansive interpretation of "claims" within the scope of § 343(r) to include a simple statement of nutrient amount of the type found on a federally required label. NYSRA seeks to reconcile the preemption provisions by arguing that states may be "free to require restaurants to disclose nutrition information" under § 343-1(a)(4), but only if such state regulations are "identical" to federal regulation of "claims" under § 343(r). (Pl.'s Letter of July 27, 2007 at 2.) If not—for example, if the regulations in any way mandate where or how such information must be displayed, or limit how it can be measured—they will be preempted under § 343-1(a)(5). Rather than reconciling the preemption provisions, such an interpretation would read out of existence the state authority preserved by § 343-1(a)(4) and would result in the preemption under § 343-1(a)(5) of virtually all state regulations requiring restaurants to provide nutrition information.

NYSRA's interpretation further ignores the structure of the NLEA and fails to draw the critical distinction between mandatory nutrient disclosures, whether required by § 343(q) or, with respect to restaurants, by state regulation, and voluntary nutrient content claims, subject to regulation under § 343(r). The fact that the source of a mandatory nutrient disclosure is a state or local government does not take the regulation out of the heartland of § 343(q) and convert a required disclosure into a voluntary claim regulated by § 343(r) and preempted by § 343-1(a)(5). The majority of state or local regulations—those that simply require restaurants to provide nutrition information—therefore are not preempted. Such regulations impose a blanket mandatory duty on all restaurants meeting a standard definition such as operating ten or more restaurants under the same name.

(See, e.g., San Francisco Amici, Exs. D, E.). There is no voluntary aspect to such a disclosure requirement and no basis for arguing that the mandated disclosures are more properly considered the regulation of voluntary claims subject to § 343(r).

Regulation 81.50, however, is not so easily categorized. It has both a voluntary aspect, in that it only applies to those restaurants that have chosen to disclose calorie content information to their customers, and a mandatory aspect, in that it requires that restaurants calculate and post calorie values in a certain manner. Importantly, the mandatory aspect of Regulation 81.50 operates in precisely the same manner as § 343(r) and its implementing regulations. If a food purveyor chooses to make a nutrient content claim, then it is subjected to mandatory regulations under § 343(r) regarding the nature and content of its voluntary claim. Likewise, if a restaurant chooses to make calorie content information available, then it is subjected to a mandatory requirement under Regulation 81.50 of posting such information on menu boards and menus.¹⁷ By making its requirements contingent on a *voluntary* claim, Regulation 81.50 directly implicates § 343(r) and its corresponding preemption provision.¹⁸ New York City, although free to enact mandatory disclosure requirements of the nature sanctioned by § 343(q) (and proposed or enacted in other jurisdictions), has adopted a regulatory approach that puts it

¹⁷ If a restaurant removes its voluntarily provided nutrition information after March 1, 2007, it would appear to fall outside the qualifying terms of Regulation 81.50 and, thereby, be freed from its responsibility to post calorie values on its menus and menu boards. (See Frieden Decl., Ex. 12 (applying to restaurants “that *make* calories information publicly available on or after March 1, 2007” (emphasis added))). In any event, the act subjecting a restaurant in the first instance to Regulation 81.50 would remain a voluntary nutrient content claim, thus bringing the regulation within the ambit of § 343(r).

¹⁸ New York City chose to limit the applicability of Regulation 81.50 to restaurants that had already disclosed calorie information in order to make the regulation less burdensome; restaurants would not have to “analyze [their] menu from scratch.” (Frieden Decl. ¶ 41.) While the City’s proffered reason is laudable, it does not alter the fact that its decision brought the regulation within the scope of the NLEA’s preemption provisions.

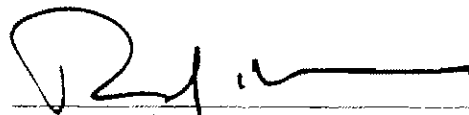
in the heartland of § 343(r) and has subjected its regulation to preemption under § 343-1(a)(5).

CONCLUSION

For the foregoing reasons, plaintiff's motion for summary judgment that Regulation 81.50 is preempted is GRANTED. Regulation 81.50 is without effect, and New York City is permanently enjoined from enforcing it. Having found the subject regulation preempted, the Court need not and does not address the parties' First Amendment arguments.

SO ORDERED.

Dated: New York, New York
September 11, 2007



Richard J. Holwell
United States District Judge

Index No. 07 CV.5710

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NEW YORK STATE RESTAURANT
ASSOCIATION,

Plaintiff,

- against -

NEW YORK CITY BOARD OF HEALTH, et al.,

Defendants.

NOTICE OF APPEAL

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Due and timely service is hereby admitted.

New York, N.Y., 2007.....

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